

Application No. 10/562,517
Responsive to Office Action dated August 22, 2008
Paper Dated February 19, 2009
Attorney Docket No. 4400-053057

REMARKS

This Amendment is responsive to the Office Action dated August 22, 2008.

There are only two rejections in the outstanding Office Action, namely, the asserted failure of claim 18 to specify kg “of what” and an asserted obviousness rejection of claims 1-18 over U.S. Patent No. 5,973,004 to Howard taken in view of U.S. Patent No. 6,479,069 to Hamilton.

The Examiner acknowledges that the Howard prior art does not disclose the presence of niacin in a composition such as that claimed. Hamilton is cited to provide the assertedly missing teaching of adding niacin to the composition, and method. However, neither reference nor the two taken together teach the use of L-carnitine, acetyl-L-carnitine, pantothenate and niacinamide in partially closed method and composition claims that recite “consisting essentially of” to highlight the importance of the four-way components specifically. By means of the amendments filed herewith, therefore, the claims define over, and are nonobvious over, the prior art cited by the Examiner.

More particularly, the niacin component of Hamilton is an incidental constituent of the “Boost” starting material to which Hamilton adds further nutritional components. Indeed, reading Hamilton as a whole especially in consultation of its claims, the presence of niacin is somewhere between incidental to completely unimportant and is not recited in the main claimed compositions at all. By contrast, the present inventor has discovered something wholly unexpected: when L-carnitine, acetyl-L-carnitine, pantothenate and niacinamide are all affirmatively given together (not in a larger multi-nutritional supplement, but combined together specifically for the stated indications) the L-carnitine, acetyl-L-carnitine and pantothenate remediate the cardiovascular or energy indications (typically cardiomyopathy or seizures) and the niacin prevents later development of pellagra. This two-stage benefit to a four-part composition (and method) represents new and unexpected results—no one (absent reading the present specification) would realize the need to add niacinamide to a L-carnitine, acetyl-L-carnitine and pantothenate supplement particularly because niacin deficiency in the developed world is virtually unheard of at this writing. Pet dogs, for example, receive more than adequate niacin in their diets no matter which dog food or feed is used, and the medical benefit of the added niacin to the L-carnitine, acetyl-L-carnitine and pantothenate combination is in addition to normal dietary amounts of niacin the mammal is already consuming. The added niacin specifically

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stops later pellagra in the mammal or patient. Indeed, before the ability to reverse cardiomyopathy or seizures using L-carnitine, acetyl-L-carnitine and pantothenate, it was not known that if one could overcome cardiomyopathy or seizures in a mammal that pellagra would typically follow, even when there was no dietary niacin deficiency. One way of looking at the nonobviousness of the present invention, then, is that it contains its own time-release two stage medicament—the L-carnitine, acetyl-L-carnitine and pantothenate treat or cure the energy-related disease or syndrome and the niacin prevents the pellagra that predictably follows even when the mammal or patient consumes a non-niacin-deficient diet otherwise. Nothing in Dr. Howard's own prior work, or certainly in the Hamilton patent, leads one skilled in the art to this surprising and novel combination of four key constituents or the unexpected medical result and health benefit.

In part because all the claims have now been limited to the “consisting essentially of” transitional phrase, and because both Howard and Hamilton identify other nutritional components (coenzyme Q, ubiquinone, etc.) that are irrelevant to achieving the unexpected results of the invention, the present claims are in condition for allowance as amended. In other words, one consulting Howard and Hamilton had a much larger list of nutritional components to select from than just the key four recited constituents limited as to “consisting essentially of.” One skilled in the art could not have learned the critical combinations claimed from the larger lists of nutritional components combined in the cited prior art. The four key ingredients, plus any incidental excipients or preservatives, give new and unexpected results and thus are entitled to a patent having partially closed claims as described above. Indeed, applicant intends for its claims to be construed so as to preclude the presence of any other significant nutritional component (other than excipients and preservatives) in part because modern nutraceutical technology is finally warning against shotgun approaches to nutritional supplementation, which particularly in disease or syndrome indications often either do no good at all or create unwanted synergies or side effects from too many concentrated nutrients delivered all at once. Of course other nutritional components will be present in the diet—but they ought not to be present in the claimed composition nor given at the same time as the components administered according to the present method.

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Claim 18 has been amended herewith to specify that the mg/kg are mg per kg of said mammal, to satisfy the Examiner's concern.

CONCLUSION

Entry of the above amendments, and allowance of claims 1-8, 10, 12 and 14-18, are respectfully requested.

If any addition issue or matter remains for resolution prior to the Examiners' issuance of a Notice of Allowance, the undersigned would very much appreciate a telephone call at the telephone number listed below.

Respectfully submitted,
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